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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,353

10/10/2002

Guenther Eberz

Mo6996/LeA

8113

7590

10/24/2006

Bayer Corporation  
Patent Department  
100 Bayer Road  
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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/069,353

Applicant(s)

EBERZ ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 73-86 and 88-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-86, 88 and 89 is/are rejected.
- 7) ☒ Claim(s) 90 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/22/02 & 10/10/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/28/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 73-86 and 88-90 are pending.

Applicants' amendments filed April 25 and August 9, 2006 are acknowledged.

Applicants' response has been fully considered. Claim 73 has been amended, and new claims 88-90 have been added. Therefore, claims 73-86 and 88-90 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claims 7, 11 and 65 is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed April 25, 2006.

### **Withdrawn Claim Rejections - 35 USC § 101**

3. The previous rejection of claims 1-5, 7 and 11, under 35 U.S.C. 101, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed April 25, 2006.

### **Withdrawn Claim Rejections - 35 USC § 112**

4. The previous rejection of claims 1-5, 14-30, 65, under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claims in the amendment filed April 25, 2006.
5. The previous rejection of claims 7 and 11, under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed April 25, 2006.

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6. The previous rejection of claim 18, under 35 U.S.C. 112, first paragraph, regarding deposit of biological materials, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed April 25, 2006. The new claim 90 meets the requirement for deposit of biological materials.

7. The previous rejection of claims 1-5, 7, 14-30, 65 and 73-86, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at pages 5-6 in the amendment filed April 25, 2006.

**Withdrawn Claim Rejections - 35 USC § 102**

8. The previous rejection of claims 1-5, 7, 11, 73 and 83 under 35 U.S.C. 102(e) as being anticipated by Baltz et al. (U. S. Patent 6,143,526), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment of the claim, and applicants' response page 6 in the amendments filed April 25 and August 9, 2006.

***Claim Objections***

9. Claim 1 is objected to because of the use of the term "SEQ ID No.1". Use of the term "SEQ ID NO:1" is suggested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 73-86 and 88-89 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 73-86 and 88-89 are directed to a vector for heterologous expression of a gene cluster for spinosyn biosynthesis, comprising a DNA fragment larger than 40 kb wherein the DNA fragment comprises a nucleic acid comprising at least a part sequence selected from (a) SEQ ID NO:1, (b) a sequence which is complementary to a sequence defined in (a) (read as a sequence which is complementary to a fragment or full length of SEQ ID NO:1) and (c) a sequence which, due to the degeneracy of the genetic code, codes for the same amino acid sequences as a sequence defined in (a) or (b); and a host cell comprising the vector. While the specification discloses the specific nucleic acid sequence (e.g., SEQ ID NO:7, ORF1) which encodes a specific enzyme (e.g., SEQ ID NO:8, methyltransferase) involved in the biosynthesis of spinosyn (pages 12-18), and specific BAC clone (e.g., DSM 13010, DSM 13011, DSM 13012, P11/G6, P11/B10, P8/G11) comprising specific gene clusters having defined nucleic acid sequences (Fig. 7; SEQ ID NO:1), the specification does not describe a vector for heterologous expression of a gene cluster for spinosyn biosynthesis, comprising a nucleotide sequence that is complementary to a fragment of SEQ ID NO:1 and larger than 40 kb, and the sequence can encode amino acid sequences involved in spinosyn biosynthesis as the SEQ ID NO:1. Furthermore, the specification has not identified any nucleotide sequence that is complementary to a fragment of SEQ ID NO:1 and can encode amino acid sequences involved in spinosyn biosynthesis. Without guidance on structure to function/activity for the nucleotide sequence that is complementary to a fragment of SEQ ID NO:1 and larger than 40 kb, one skilled in the art would not know whether the nucleotide sequence can encode amino acid sequences involved in

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spinosyn biosynthesis. The lack of description of the correlation of structure to activity of nucleotide sequences that are complementary to a fragment of SEQ ID NO:1 and the lack of representative species for the nucleotide variants as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Response to Arguments*

Applicants indicate the amended claims do not involve or overcome the rejection (page 5 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because the claims encompass a nucleotide sequence that is complementary to a fragment of SEQ ID NO:1 and larger than 40 kb, where the sequence can encode amino acid sequences involved in spinosyn biosynthesis as the SEQ ID NO:1, where the sequences are not sufficiently described in the specification as indicated above. Therefore, a skilled artisan would not recognize applicants were in possession of the claimed invention.

*Claim Objections*

11. Claim 90 is objected to because the claim is dependent from a rejected claim.

*Conclusion*

12. Claims 73-86 and 88-89 are rejected; and claim 90 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

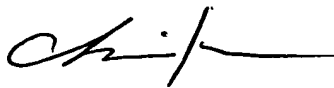
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Chih-Min Kam, Ph. D.

Primary Patent Examiner



*Primary*

**CHIH-MIN KAM  
PATENT EXAMINER**

CMK

October 19, 2006